

This listing of claims will replace all prior versions and listings of claims in the application:

**LISTING OF CLAIMS:**

1                   Claim 1 (currently amended): A unit dosage form as an adjunct to biguanide or  
2                   sulfonylurea therapy for supporting mitochondrial metabolism as a method for the prevention,  
3                   management and clinical amelioration of insulin resistance and type 2 diabetes and conditions  
4                   giving rise thereto, said unit dosage form comprising as active ingredients:

5                   (a) L-carnitine,  
6                   (b) ascorbic acid,  
7                   (c) choline,  
8                   (d) ~~(e)~~ taurine,  
9                   (e) ~~(f)~~ folic acid, and  
10                   (f) ~~(g)~~ magnesium.

1                   Claim 2 (original): A unit dosage form in accordance with claim 1 in which said  
2                   active ingredients are formulated as a substantially homogeneous tablet or capsule that releases  
3                   all of said active ingredients into the stomach upon ingestion for contact with gastric fluid.

1                   Claim 3 (currently amended): A unit dosage form in accordance with claim 2 in  
2                   which:

3                   (a) said L-carnitine is in an amount ranging from about 90 mg to about 2500 mg,  
4                   and  
5                   (b) said ascorbic acid is in an amount ranging from about 75 mg to about 3000  
6                   mg,  
7                   (c) said choline is in an amount ranging from about 15 mg to about 250 mg,  
8                   (d) said taurine is in an amount ranging from about 75 mg to about 3000 mg,  
9                   (e) said magnesium is in an amount ranging from about 30 mg to about 1000 mg,  
10                   and

11 (f) ~~(d)~~ said folic acid is in an amount ranging from about 0.03 mg to about 2 mg.

1 Claims 4-6 (canceled)

1 Claim 7 (original): A unit dosage form as an adjunct to biguanide or sulfonylurea  
2 therapy specifically for nocturnal use as a method for the prevention, management and clinical  
3 amelioration of insulin resistance and type 2 diabetes and conditions giving rise thereto, said unit  
4 dosage form comprising as active ingredients:

5 (a) melatonin,  
6 (b) L-carnitine,  
7 (c) ubiquinone,  
8 (d) folic acid,  
9 (e) magnesium, and  
10 (f) L-arginine.

1 Claim 8 (original): A unit dosage form in accordance with claim 7 in which said  
2 active ingredients are formulated as a substantially homogeneous tablet or capsule that releases  
3 all of said active ingredients into the stomach upon ingestion for contact with gastric fluid.

1 Claim 9 (original): A unit dosage form in accordance with claim 8 in which:  
2 (a) said melatonin is in an amount ranging from about 0.15 mg to about 7.5 mg,  
3 (b) said L-carnitine is in an amount ranging from about 90 mg to about 2500 mg,  
4 (c) said ubiquinone is in an amount ranging from about 4.5 mg to about 225 mg,  
5 (d) said folic acid is in an amount ranging from about 0.03 mg to about 2 mg,  
6 (e) said magnesium is in an amount ranging from about 30 mg to about 1000 mg,  
7 and  
8 (f) said L-arginine is in an amount ranging from about 75 mg to about 3100 mg.

1 Claim 10 (original): A unit dosage form for use as an adjunct to biguanide or  
2 sulfonylurea therapy alternative to insulin for use as a method for the prevention, management

3 and clinical amelioration of insulin resistance and type 2 diabetes and conditions giving rise  
4 thereto, said unit dosage form comprising as active ingredients:

5 (a) vanadium,  
6 (b) L-arginine,  
7 (c) chromium, and  
8 (d) zinc.

1 Claim 11 (original): A unit dosage form in accordance with claim 10 in which  
2 said active ingredients are formulated as a substantially homogeneous tablet or capsule that  
3 releases all of said active ingredients into the stomach upon ingestion for contact with gastric  
4 fluid.

1 Claim 12 (original): A unit dosage form in accordance with claim 11 in which:  
2 (a) said vanadium is in an amount ranging from about 7.5 mg to about 375 mg,  
3 (b) said L-arginine is in an amount ranging from about 75 mg to about 3100 mg,  
4 (c) said chromium is in an amount ranging from about 0.01 mg to about 0.63 mg,  
5 and  
6 (d) said zinc is in an amount ranging from about 1.5 mg to about 100 mg.

1 Claim 13 (original): A unit dosage form in accordance with claim 1 in which said  
2 unit dosage form is a bilayer tablet comprising an immediate-release layer and a sustained-  
3 release layer, said active ingredients are distributed between said immediate-release layer and  
4 said sustained-release layer in the following approximate proportions expressed as relative  
5 weight percents:

	Immediate-Release Layer	Sustained-Release Layer
7	L, carnitine	40-60%
8	ascorbic acid	40-60%
9	choline	100%
10	folic acid	100%
11	taurine	40-60%

1 Claim 14 (canceled)

1                   Claim 15 (original): A unit dosage form in accordance with claim 7 in which said  
2   unit dosage form is a bilayer tablet comprising an immediate-release layer and a sustained-  
3   release layer, said active ingredients are distributed between said immediate-release layer and  
4   said sustained-release layer in the following approximate proportions expressed as relative  
5   weight percents:

		Immediate-Release Layer	Sustained-Release Layer
6			
7	melatonin	40-60 %	balance
8	L-carnitine	40-60%	balance
9	zinc	40%-60%	balance
10	folic acid	100%	
11	magnesium	40-60%	balance
12	ubiquinone	100%	

1                   Claim 16 (original): A unit dosage form in accordance with claim 10 in which  
2    said unit dosage form is a bilayer tablet comprising an immediate-release layer and a sustained-  
3    release layer, said active ingredients are distributed between said immediate-release layer and  
4    said sustained-release layer in the following approximate proportions expressed as relative  
5    weight percents:

		Immediate-Release Layer	Sustained-Release Layer
6			
7	vanadium	40-60 %	balance
8	L-arginine	40-60%	balance
9	chromium	40%-60%	balance
10	zinc	40%-60%	balance

1 **Claim 17 (canceled)**

1                   Claim 18 (currently amended): A unit dosage form in accordance with claims 4,  
2   7 or 10 in which said L-arginine is in the form of a member selected from the group consisting of  
3   L arginine ascorbate, bis-L arginine ascorbate, L arginine salt of a metal ion selected from the  
4   group consisting of  $Mg^{2+}$  and  $Zn^{2+}$ , bis-L arginine salt of a metal ion selected from the group  
5   consisting of  $Mg^{2+}$  and  $Zn^{2+}$ , and a complex of L arginine or bis-L arginine, a metal ion selected  
6   from the group consisting of  $Mg^{2+}$  and  $Zn^{2+}$ , and an anion selected from the group consisting of  
7   hydroxide, halide, acetate, and ascorbate.

1                   Claim 19 (original): A unit dosage form in accordance with claims 1 or 7 in  
2   which said L-carnitine is in the form of a member selected from the group consisting of L  
3   carnitine ascorbate, bis-L carnitine ascorbate, L carnitine salt of a metal ion selected from the  
4   group consisting of  $Mg^{2+}$  and  $Zn^{2+}$ , bis-L carnitine salt of a metal ion selected from the group  
5   consisting of  $Mg^{2+}$  and  $Zn^{2+}$ , and a complex of L carnitine or bis-L carnitine, a metal ion selected  
6   from the group consisting of  $Mg^{2+}$  and  $Zn^{2+}$ , and an anion selected from the group consisting of  
7   hydroxide, halide, acetate, and ascorbate.

1                   Claim 20 (original): A unit dosage form in accordance with claim 1 in which said  
2   L-taurine is in the form of a member selected from the group consisting of L taurine ascorbate,  
3   bis-L taurine ascorbate, L taurine salt of a metal ion selected from the group consisting of  $Mg^{2+}$   
4   and  $Zn^{2+}$ , bis-L taurine salt of a metal ion selected from the group consisting of  $Mg^{2+}$  and  $Zn^{2+}$ ,  
5   and a complex of L taurine or bis-L taurine, a metal ion selected from the group consisting of  
6    $Mg^{2+}$  and  $Zn^{2+}$ , and an anion selected from the group consisting of hydroxide, halide, acetate,  
7   and ascorbate.

1                   Claim 21 (original): A unit dosage form in accordance with claims 1 or 7 in  
2   which said magnesium is in the form of a member selected from the group consisting of  
3   magnesium, magnesium L-arginate, magnesium L-arginine ascorbate and bis-ascorbate,  
4   magnesium  $\alpha$ -lipoate, magnesium  $\alpha$ -lipoate ascorbate and bis-ascorbate, magnesium taurate,  
5   magnesium taurine ascorbate and bis-ascorbate, magnesium L-acetylcysteine, magnesium L-

6 carnitine, magnesium L-carnitine ascorbate and bis-ascorbate, magnesium ascorbate and  
7 magnesium bis-ascorbate.

1                   Claim 22 (original): A unit dosage form in accordance with claim 10 in which  
2 said zinc is in the form of a member selected from the group consisting of zinc halide, zinc  
3 sulfate, zinc L-carnitine, zinc L-carnitine ascorbate and bis-ascorbate, zinc taurate, zinc taurine  
4 ascorbate and bis-ascorbate, zinc L-arginate, zinc L-arginine ascorbate and bis-ascorbate, zinc L-  
5 carnitine, zinc L-carnitine ascorbate and bis-ascorbate, zinc phosphate, zinc acetate, zinc  
6 ascorbate, and zinc bis-ascorbate.

1                   Claim 23 (original): A unit dosage form in accordance with claim 10 in which  
2 said vanadium is in the form of a member selected from the group consisting of vanadate,  
3 peroxovanadate, vanadyl sulfate salts, and bis(maltolato)oxovanadium(IV).

1                   Claims 24-25 (canceled)

1                   Claim 26 (original): A unit dosage form in accordance with claim 10 in which  
2 said chromium is in the form of a member selected from the group consisting of chromium  
3 dinicotinate, and chromium tripicolinate.

1                   Claim 27 (currently amended): A method for treating a patient who is undergoing  
2 biguanide therapy for the prevention, management, and clinical amelioration of insulin resistance  
3 and type 2 diabetes and conditions giving rise thereto, to reduce undesirable physiological side  
4 effects, and enhance the therapeutic effectiveness, of said biguanide therapy, said method  
5 comprising administering to said patient a unit dosage form comprising as active ingredients:  
6                   (a) L-carnitine,  
7                   (b) ascorbic acid,  
8                   (c) choline,  
9                   (d) (e) taurine,  
10                   (e) (f) folic acid, and  
11                   (f) (g) magnesium.

1           Claim 28 (original): A method in accordance with claim 27 in which said active  
2 ingredients are formulated as a substantially homogeneous tablet or capsule that releases all of  
3 said active ingredients into the stomach upon ingestion for contact with gastric fluid.

1           Claim 29 (currently amended): A method in accordance with claim 28 in which:  
2           (a) said L-carnitine is in an amount ranging from about 90 mg to about 2500 mg,  
3           and  
4           (b) said ascorbic acid is in an amount ranging from about 75 mg to about 3000  
5           mg,  
6           (c) said choline is in an amount ranging from about 15 mg to about 250 mg,  
7           (d) said taurine is in an amount ranging from about 75 mg to about 3000 mg,  
8           (e) said magnesium is in an amount ranging from about 30 mg to about 1000 mg,  
9           and  
10           (f) ~~(d)~~ said folic acid is in an amount ranging from about 0.03 mg to about 2 mg.

1           Claims 30-32 (canceled)

1           Claim 33 (original): A method for treating a patient who is undergoing nocturnal  
2 biguanide therapy for the preservation of plasma and mitochondrial membrane integrity for the  
3 prevention, management, and clinical amelioration of insulin resistance and type 2 diabetes and  
4 conditions giving rise thereto, to reduce undesirable physiological side effects, and enhance the  
5 therapeutic effectiveness, of said biguanide therapy, said method comprising administering to  
6 said patient a unit dosage form comprising as active ingredients:

7           (a) melatonin,  
8           (b) L-Carnitine,  
9           (c) ubiquinone,  
10           (d) folic acid,  
11           (e) magnesium, and  
12           (f) L-arginine.

1                   Claim 34 (original): A method in accordance with claim 33 in which said active  
2 ingredients are formulated as a substantially homogeneous tablet or capsule that releases all of  
3 said active ingredients into the stomach upon ingestion for contact with gastric fluid.

1                   Claim 35 (original): A method in accordance with claim 34 in which:  
2                   (a) said melatonin is in an amount ranging from about 0.15 mg to about 7.5 mg,  
3                   (b) said L-carnitine is in an amount ranging from about 90 mg to about 2500 mg,  
4                   (c) said ubiquinone is in an amount ranging from about 4.5 mg to about 225 mg,  
5                   (d) said folic acid is in an amount ranging from about 0.03 mg to about 2 mg,  
6                   (e) said magnesium is in an amount ranging from about 30 mg to about 1000 mg,  
7                   and  
8                   (f) said L-arginine is in an amount ranging from about 75 mg to about 3100 mg.

1                   Claim 36 (original): A method for treating a patient who is undergoing biguanide  
2 therapy as an alternative to insulin for the prevention, management, and clinical amelioration of  
3 insulin resistance and type 2 diabetes and conditions giving rise thereto, to reduce undesirable  
4 physiological side effects, and enhance the therapeutic effectiveness, of said biguanide therapy,  
5 said method comprising administering to said patient a unit dosage form comprising as active  
6 ingredients:

7                   (a) vanadium,  
8                   (b) L-arginine,  
9                   (c) chromium, and  
10                  (d) zinc.

1                   Claim 37 (original): A method in accordance with claim 36 in which said active  
2 ingredients are formulated as a substantially homogeneous tablet or capsule that releases all of  
3 said active ingredients into the stomach upon ingestion for contact with gastric fluid.

1                   Claim 38 (original): A method in accordance with claim 37 in which:  
2                   (a) said vanadium is in an amount ranging from about 7.5 mg to about 375 mg,

3 (b) said L-arginine is in an amount ranging from about 75 mg to about 3100 mg,  
4 (c) said chromium is in an amount ranging from about 0.01 mg to about 0.63 mg,  
5 and  
6 (d) said zinc is in an amount ranging from about 1.5 mg to about 100 mg.

		Immediate-Release Layer	Sustained-Release Layer
6			
7	L, carnitine	40-60%	balance
8	ascorbic acid	40-60%	balance
9	choline	100%	
10	folic acid	100%	
11	taurine	40-60%	balance
12	magnesium	40-60%	balance

1 **Claim 40 (canceled)**

		Immediate-Release Layer	Sustained-Release Layer
6			
7	melatonin	40-60 %	balance
8	L-carnitine	40-60%	balance
9	zinc	40%-60%	balance
10	folic acid	100%	

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11	magnesium	40-60%	balance
12	ubiquinone	100%	

13                   Claim 42 (original): A method in accordance with claim 36 in which said unit  
14 dosage form is a bilayer tablet comprising an immediate-release layer and a sustained-release  
15 layer, said active ingredients are distributed between said immediate-release layer and said  
16 sustained-release layer in the following approximate proportions expressed as relative weight  
17 percents:

		Immediate-Release Layer	Sustained-Release Layer
19	vanadium	40-60 %	balance
20	L-arginine	40-60%	balance
21	chromium	40%-60%	balance
22	zinc	40%-60%	balance

1                   Claim 43 (canceled)

1                   Claim 44 (currently amended): A method in accordance with claims 30, 33, or 36  
2 in which said L-arginine is in the form of a member selected from the group consisting of L  
3 arginine ascorbate, bis-L arginine ascorbate, L arginine salt of a metal ion selected from the  
4 group consisting of  $Mg^{2+}$  and  $Zn^{2+}$ , bis-L arginine salt of a metal ion selected from the group  
5 consisting of  $Mg^{2+}$  and  $Zn^{2+}$ , and a complex of L arginine or bis-L arginine, a metal ion selected  
6 from the group consisting of  $Mg^{2+}$  and  $Zn^{2+}$ , and an anion selected from the group consisting of  
7 hydroxide, halide, acetate, and ascorbate.

1                   Claim 45 (original): A method in accordance with claims 27 or 33 in which said  
2 L-carnitine is in the form of a member selected from the group consisting of L carnitine  
3 ascorbate, bis-L carnitine ascorbate, L carnitine salt of a metal ion selected from the group  
4 consisting of  $Mg^{2+}$  and  $Zn^{2+}$ , bis-L carnitine salt of a metal ion selected from the group  
5 consisting of  $Mg^{2+}$  and  $Zn^{2+}$ , and a complex of L carnitine or bis-L carnitine, a metal ion selected

6 from the group consisting of  $Mg^{2+}$  and  $Zn^{2+}$ , and an anion selected from the group consisting of  
7 hydroxide, halide, acetate, and ascorbate.

1                   Claim 46 (original): A method in accordance with claim 27 in which said L-  
2 taurine is in the form of a member selected from the group consisting of L taurine ascorbate, bis-  
3 L taurine ascorbate, L taurine salt of a metal ion selected from the group consisting of  $Mg^{2+}$  and  
4  $Zn^{2+}$ , bis-L taurine salt of a metal ion selected from the group consisting of  $Mg^{2+}$  and  $Zn^{2+}$ , and a  
5 complex of L taurine or bis-L taurine, a metal ion selected from the group consisting of  $Mg^{2+}$  and  
6  $Zn^{2+}$ , and an anion selected from the group consisting of hydroxide, halide, acetate, and  
7 ascorbate.

1                   Claim 47 (original): A method in accordance with claims 27 or 33 in which said  
2 magnesium is in the form of a member selected from the group consisting of magnesium,  
3 magnesium L-arginate, magnesium L-arginine ascorbate and bis-ascorbate, magnesium  $\alpha$ -  
4 lipoate, magnesium  $\alpha$ -lipoate ascorbate and bis-ascorbate, magnesium taurate, magnesium  
5 taurine ascorbate and bis-ascorbate, magnesium L-acetylcysteine, magnesium L-carnitiate,  
6 magnesium L-carnitine ascorbate and bis-ascorbate, magnesium ascorbate and magnesium bis-  
7 ascorbate.

1                   Claim 48 (original): A method in accordance with claim 36 in which said zinc is  
2 in the form of a member selected from the group consisting of zinc halide, zinc sulfate, zinc L-  
3 carnitiate, zinc L-carnitiate ascorbate and bis-ascorbate, zinc taurate, zinc taurine ascorbate and  
4 bis-ascorbate, zinc L-arginate, zinc L-arginine ascorbate and bis-ascorbate, zinc L-carnitiate, zinc  
5 L-carnitine ascorbate and bis-ascorbate, zinc phosphate, zinc acetate, zinc ascorbate, and zinc  
6 bis-ascorbate.

1                   Claim 49 (original): A method in accordance with claim 36 in which said  
2 vanadium is in the form of a member selected from the group consisting of vanadate,  
3 peroxovanadate, vanadyl sulfate salts, and bis(maltolato)oxovanadium(IV).

1                   Claim 50 (currently amended): A method in accordance with claim claims 30 or  
2    32 in which said D, $\alpha$  tocopherol is present in the form of a member selected from the group  
3    consisting of D, $\alpha$  tocopherol succinate, D,  $\alpha$ -tocopherol nicotinate, D,  $\alpha$ -tocopherol picolinate,  
4    D, $\alpha$  tocopherol acetate, and tocotrienol.

1                   Claim 51 (currently amended): A method in accordance with claim claims 40 or  
2    50 in which said tocotrienol is present in the form of a member selected from the group  
3    consisting of tocotrienol succinate, tocotrienol nicotinate, tocotrienol picolinate, and tocotrienol  
4    acetate.

1                   Claim 52 (original): A method in accordance with claim 36 in which said  
2    chromium is in the form of a member selected from the group consisting of chromium  
3    dinicotinate, and chromium tripicolinate.

1                   Claim 53 (currently amended): A method for treating a patient who is undergoing  
2    sulfonylurea therapy for the prevention, management, and clinical amelioration of insulin  
3    resistance and type 2 diabetes and conditions giving rise thereto, to reduce undesirable  
4    physiological side effects, and enhance the therapeutic effectiveness, of said sulfonylurea  
5    therapy, said method comprising administering to said patient a unit dosage form comprising as  
6    active ingredients:

7                   (a) L-carnitine,  
8                   (b) Ascorbic acid,  
9                   (c) Choline,  
10                  (d) ~~(e)~~ Taurine,  
11                  (e) ~~(f)~~ Folic Acid, and  
12                  (f) ~~(g)~~ Magnesium.

1                   Claim 54 (original): A method in accordance with claim 53 in which said active  
2    ingredients are formulated as a substantially homogeneous tablet or capsule that releases all of  
3    said active ingredients into the stomach upon ingestion for contact with gastric fluid.

1                   Claim 55 (currently amended): A method in accordance with claim 54 in which:  
2                   (a) said L-carnitine is in an amount ranging from about 90 mg to about 2500 mg,  
3                   and  
4                   (b) said ascorbic acid is in an amount ranging from about 75 mg to about 3000  
5                   mg,  
6                   (c) said choline is in an amount ranging from about 15 mg to about 250 mg,  
7                   (d) said taurine is in an amount ranging from about 75 mg to about 3000 mg,  
8                   (e) said magnesium is in an amount ranging from about 30 mg to about 1000 mg,  
9                   and  
10                  (f) ~~(d)~~ said folic acid is in an amount ranging from about 0.03 mg to about 2 mg.

1                   Claims 56-58 (canceled)

1                   Claim 59 (original): A method for treating a patient who is undergoing nocturnal  
2                   sulfonylurea therapy for the preservation of plasma and mitochondrial membrane integrity for  
3                   the prevention, management, and clinical amelioration of insulin resistance and type 2 diabetes  
4                   and conditions giving rise thereto, to reduce undesirable physiological side effects, and enhance  
5                   the therapeutic effectiveness, of said sulfonylurea therapy, said method comprising administering  
6                   to said patient a unit dosage form comprising as active ingredients:  
7                   (a) melatonin,  
8                   (b) L-Carnitine,  
9                   (c) ubiquinone,  
10                  (d) folic acid,  
11                  (e) magnesium, and  
12                  (f) L-arginine.

1                   Claim 60 (original): A method in accordance with claim 59 in which said active  
2                   ingredients are formulated as a substantially homogeneous tablet or capsule that releases all of  
3                   said active ingredients into the stomach upon ingestion for contact with gastric fluid.

1                   Claim 61 (original): A method in accordance with claim 60 in which:  
2                   (a) said melatonin is in an amount ranging from about 0.15 mg to about 7.5 mg,  
3                   (b) said L-carnitine is in an amount ranging from about 90 mg to about 2500 mg,  
4                   (c) said ubiquinone is in an amount ranging from about 4.5 mg to about 225 mg,  
5                   (d) said folic acid is in an amount ranging from about 0.03 mg to about 2 mg,  
6                   (e) said magnesium is in an amount ranging from about 30 mg to about 1000 mg,  
7                   and  
8                   (f) said L-arginine is in an amount ranging from about 75 mg to about 3100 mg.

1                   Claim 62 (original): A method for treating a patient who is undergoing  
2                   sulfonylurea therapy as an alternative to insulin for the prevention, management, and clinical  
3                   amelioration of insulin resistance and type 2 diabetes and conditions giving rise thereto, to  
4                   reduce undesirable physiological side effects, and enhance the therapeutic effectiveness, of said  
5                   sulfonylurea therapy, said method comprising administering to said patient a unit dosage form  
6                   comprising as active ingredients:  
7                   (a) vanadium,  
8                   (b) L-arginine,  
9                   (c) chromium, and  
10                  (d) zinc.

1                   Claim 63 (original): A method in accordance with claim 62 in which said active  
2                   ingredients are formulated as a substantially homogeneous tablet or capsule that releases all of  
3                   said active ingredients into the stomach upon ingestion for contact with gastric fluid.

1                   Claim 64 (original): A method in accordance with claim 63 in which:  
2                   (a) said vanadium is in an amount ranging from about 7.5 mg to about 375 mg,  
3                   (b) said L-arginine is in an amount ranging from about 75 mg to about 3100 mg,  
4                   (c) said chromium is in an amount ranging from about 0.01 mg to about 0.63 mg,  
5                   and

6 (d) said zinc is in an amount ranging from about 1.5 mg to about 100 mg.

1                   Claim 65 (original): A method in accordance with claim 53 in which said unit  
2 dosage form is a bilayer tablet comprising an immediate-release layer and a sustained-release  
3 layer, said active ingredients are distributed between said immediate-release layer and said  
4 sustained-release layer in the following approximate proportions expressed as relative weight  
5 percents:

	Immediate-Release Layer	Sustained-Release Layer
7	L, carnitine                   40-60%	balance
8	ascorbic acid                 40-60%	balance
9	choline                         100%	
10	folic acid                     100%	
11	taurine                         40-60%	balance
12	magnesium                     40-60%	balance

1                   Claim 66 (canceled)

1                   Claim 67 (original): A method in accordance with claim 59 in which said unit  
2 dosage form is a bilayer tablet comprising an immediate-release layer and a sustained-release  
3 layer, said active ingredients are distributed between said immediate-release layer and said  
4 sustained-release layer in the following approximate proportions expressed as relative weight  
5 percents:

	Immediate-Release Layer	Sustained-Release Layer
7	melatonin                     40-60 %	balance
8	L-carnitine                   40-60%	balance
9	zinc                            40%-60%	balance
10	folic acid                    100%	
11	magnesium                    40-60%	balance
12	ubiquinone                    100%	

13                   Claim 68 (original): A method in accordance with claim 62 in which said unit  
14 dosage form is a bilayer tablet comprising an immediate-release layer and a sustained-release  
15 layer, said active ingredients are distributed between said immediate-release layer and said  
16 sustained-release layer in the following approximate proportions expressed as relative weight  
17 percents:

		Immediate-Release Layer	Sustained-Release Layer
19	vanadium	40-60 %	balance
20	L-arginine	40-60%	balance
21	chromium	40%-60%	balance
22	zinc	40%-60%	balance

1                   Claim 69 (canceled)

1                   Claim 70 (currently amended): A method in accordance with claims 56, 59, or 62  
2 in which said L-arginine is in the form of a member selected from the group consisting of L  
3 arginine ascorbate, bis-L arginine ascorbate, L arginine salt of a metal ion selected from the  
4 group consisting of  $Mg^{2+}$  and  $Zn^{2+}$ , bis-L arginine salt of a metal ion selected from the group  
5 consisting of  $Mg^{2+}$  and  $Zn^{2+}$ , and a complex of L arginine or bis-L arginine, a metal ion selected  
6 from the group consisting of  $Mg^{2+}$  and  $Zn^{2+}$ , and an anion selected from the group consisting of  
7 hydroxide, halide, acetate, and ascorbate.

1                   Claim 71 (original): A method in accordance with claims 53 or 59 in which said  
2 L-carnitine is in the form of a member selected from the group consisting of L carnitine  
3 ascorbate, bis-L carnitine ascorbate, L carnitine salt of a metal ion selected from the group  
4 consisting of  $Mg^{2+}$  and  $Zn^{2+}$ , bis-L carnitine salt of a metal ion selected from the group  
5 consisting of  $Mg^{2+}$  and  $Zn^{2+}$ , and a complex of L carnitine or bis-L carnitine, a metal ion selected  
6 from the group consisting of  $Mg^{2+}$  and  $Zn^{2+}$ , and an anion selected from the group consisting of  
7 hydroxide, halide, acetate, and ascorbate.

1                   Claim 72 (original): A method in accordance with claim 53 in which said L-  
2   taurine is in the form of a member selected from the group consisting of L taurine ascorbate, bis-  
3   L taurine ascorbate, L taurine salt of a metal ion selected from the group consisting of Mg<sup>2+</sup> and  
4   Zn<sup>2+</sup>, bis-L taurine salt of a metal ion selected from the group consisting of Mg<sup>2+</sup> and Zn<sup>2+</sup>, and a  
5   complex of L taurine or bis-L taurine, a metal ion selected from the group consisting of Mg<sup>2+</sup> and  
6   Zn<sup>2+</sup>, and an anion selected from the group consisting of hydroxide, halide, acetate, and  
7   ascorbate.

1                   Claim 73 (original): A method in accordance with claims 53 or 59 in which said  
2   magnesium is in the form of a member selected from the group consisting of magnesium,  
3   magnesium L-arginate, magnesium L-arginine ascorbate and bis-ascorbate, magnesium  $\alpha$ -  
4   lipoate, magnesium  $\alpha$ -lipoate ascorbate and bis-ascorbate, magnesium taurate, magnesium  
5   taurine ascorbate and bis-ascorbate, magnesium L-acetylcysteine, magnesium L-carnitiate,  
6   magnesium L-carnitine ascorbate and bis-ascorbate, magnesium ascorbate and magnesium bis-  
7   ascorbate.

1                   Claim 74 (original): A method in accordance with claim 62 in which said zinc is  
2   in the form of a member selected from the group consisting of zinc halide, zinc sulfate, zinc L-  
3   carnitiate, zinc L-carnitiate ascorbate and bis-ascorbate, zinc taurate, zinc taurine ascorbate and  
4   bis-ascorbate, zinc L-arginate, zinc L-arginine ascorbate and bis-ascorbate, zinc L-carnitiate, zinc  
5   L-carnitine ascorbate and bis-ascorbate, zinc phosphate, zinc acetate, zinc ascorbate, and zinc  
6   bis-ascorbate.

1                   Claim 75 (original): A method in accordance with claim 62 in which said  
2   vanadium is in the form of a member selected from the group consisting of vanadate,  
3   peroxovanadate, vanadyl sulfate salts, and bis(maltolato)oxovanadium(IV).

1                   Claims 76-77 (canceled)

1                   Claim 78 ((original): A method in accordance with claim 36 in which said  
2   chromium is in the form of a member selected from the group consisting of chromium  
3   dinicotinate, and chromium tripicolinate.

1                   Claim 79 (original): A method for treating a patient who is undergoing combined  
2   biguanide and combined biguanide and sulfonylurea therapy for the prevention, management,  
3   and clinical amelioration of insulin resistance and type 2 diabetes and conditions giving rise  
4   thereto, to reduce undesirable physiological side effects, and enhance the therapeutic  
5   effectiveness, of said combined biguanide and sulfonylurea therapy, said method comprising  
6   administering to said patient a unit dosage form comprising as active ingredients:

7                   (a) L-carnitine,  
8                   (b) ascorbic acid,  
9                   (c) choline,  
10                  (e) taurine,  
11                  (f) folic acid, and  
12                  (g) magnesium.

1                   Claim 80 (original): A method in accordance with claim 79 in which said active  
2   ingredients are formulated as a substantially homogeneous tablet or capsule that releases all of  
3   said active ingredients into the stomach upon ingestion for contact with gastric fluid.

1                   Claim 81 (original): A method in accordance with claim 80 in which:  
2                  (a) said L-carnitine is in an amount ranging from about 90 mg to about 2500 mg,  
3                  and  
4                  (b) said ascorbic acid is in an amount ranging from about 75 mg to about 3000  
5                  mg,  
6                  (c) said choline is in an amount ranging from about 15 mg to about 250 mg,  
7                  (d) said taurine is in an amount ranging from about 75 mg to about 3000 mg,

8 (e) said magnesium is in an amount ranging from about 30 mg to about 1000 mg,

9 and

10 (d) said folic acid is in an amount ranging from about 0.03 mg to about 2 mg.

1 Claims 82-84 (canceled)

## 8 (a) melatonin,

9 (b) L-Carnitine,

10 (c) ubiquinone,

11 (d) folic acid,

12 (e) magnesium, and

13 (f) L-arginine.

1 Claim 87 (original): A method in accordance with claim 86 in which:

2 (a) said melatonin is in an amount ranging from about 0.15 mg to about 7.5 mg,  
3 (b) said L-carnitine is in an amount ranging from about 90 mg to about 2500 mg  
4 (c) said ubiquinone is in an amount ranging from about 4.5 mg to about 225 mg,  
5 (d) said folic acid is in an amount ranging from about 0.03 mg to about 2 mg,

(e) said magnesium is in an amount ranging from about 30 mg to about 1000 mg,

7

8 (f) said L-arginine is in an amount ranging from about 75 mg to about 3100 mg.

### 7 (a) vanadium,

## 8 (b) L-arginine,

9 (c) chromium, and

10 (d) zinc.

1 Claim 90 (original): A method in accordance with claim 89 in which:

2 (a) said vanadium is in an amount ranging from about 7.5 mg to about 375 mg,

3 (b) said L-arginine is in an amount ranging from about 75 mg to about 3100 mg,

4 (c) said chromium is in an amount ranging from about 0.01 mg to about 0.63 mg,

5 and

6 (d) said zinc is in an amount ranging from about 1.5 mg to about 100 mg.

4 sustained-release layer in the following approximate proportions expressed as relative weight  
5 percents:

		Immediate-Release Layer	Sustained-Release Layer
7	L, carnitine	40-60%	balance
8	ascorbic acid	40-60%	balance
9	choline	100%	
10	folic acid	100%	
11	taurine	40-60%	balance
12	magnesium	40-60%	balance

1                   Claim 92 (canceled)

1                   Claim 93 (original): A method in accordance with claim 85 in which said unit  
2 dosage form is a bilayer tablet comprising an immediate-release layer and a sustained-release  
3 layer, said active ingredients are distributed between said immediate-release layer and said  
4 sustained-release layer in the following approximate proportions expressed as relative weight  
5 percents:

		Immediate-Release Layer	Sustained-Release Layer
7	melatonin	40-60 %	balance
8	L-carnitine	40-60%	balance
9	zinc	40%-60%	balance
10	folic acid	100%	
11	magnesium	40-60%	balance
12	ubiquinone	100%	

1                   Claim 94 (original): A method in accordance with claim 88 in which said unit  
2 dosage form is a bilayer tablet comprising an immediate-release layer and a sustained-release  
3 layer, said active ingredients are distributed between said immediate-release layer and said  
4 sustained-release layer in the following approximate proportions expressed as relative weight  
5 percents:

		Immediate-Release Layer	Sustained-Release Layer
6			
7	vanadium	40-60 %	balance
8	L-arginine	40-60%	balance
9	chromium	40%-60%	balance
10	zinc	40%-60%	balance

1                   Claim 95 (canceled)

1                   Claim 96 (currently amended): A method in accordance with claims 82, 85, or 88  
2    in which said L-arginine is in the form of a member selected from the group consisting of L  
3    arginine ascorbate, bis-L arginine ascorbate, L arginine salt of a metal ion selected from the  
4    group consisting of  $Mg^{2+}$  and  $Zn^{2+}$ , bis-L arginine salt of a metal ion selected from the group  
5    consisting of  $Mg^{2+}$  and  $Zn^{2+}$ , and a complex of L arginine or bis-L arginine, a metal ion selected  
6    from the group consisting of  $Mg^{2+}$  and  $Zn^{2+}$ , and an anion selected from the group consisting of  
7    hydroxide, halide, acetate, and ascorbate.

1                   Claim 97 (original): A method in accordance with claims 78 or 85 in which said  
2    L-carnitine is in the form of a member selected from the group consisting of L carnitine  
3    ascorbate, bis-L carnitine ascorbate, L carnitine salt of a metal ion selected from the group  
4    consisting of  $Mg^{2+}$  and  $Zn^{2+}$ , bis-L carnitine salt of a metal ion selected from the group  
5    consisting of  $Mg^{2+}$  and  $Zn^{2+}$ , and a complex of L carnitine or bis-L carnitine, a metal ion selected  
6    from the group consisting of  $Mg^{2+}$  and  $Zn^{2+}$ , and an anion selected from the group consisting of  
7    hydroxide, halide, acetate, and ascorbate.

1                   Claim 98 (original): A method in accordance with claim 78 in which said L-  
2    taurine is in the form of a member selected from the group consisting of L taurine ascorbate, bis-  
3    L taurine ascorbate, L taurine salt of a metal ion selected from the group consisting of  $Mg^{2+}$  and  
4     $Zn^{2+}$ , bis-L taurine salt of a metal ion selected from the group consisting of  $Mg^{2+}$  and  $Zn^{2+}$ , and a  
5    complex of L taurine or bis-L taurine, a metal ion selected from the group consisting of  $Mg^{2+}$  and

6       Zn<sup>2+</sup>, and an anion selected from the group consisting of hydroxide, halide, acetate, and  
7       ascorbate.

1               Claim 99 (original): A method in accordance with claims 79 or 85 in which said  
2       magnesium is in the form of a member selected from the group consisting of magnesium,  
3       magnesium L-arginate, magnesium L-arginine ascorbate and bis-ascorbate, magnesium  $\alpha$ -  
4       lipoate, magnesium  $\alpha$ -lipoate ascorbate and bis-ascorbate, magnesium taurate, magnesium  
5       taurine ascorbate and bis-ascorbate, magnesium L-acetylcysteine, magnesium L-carnitiate,  
6       magnesium L-carnitine ascorbate and bis-ascorbate, magnesium ascorbate and magnesium bis-  
7       ascorbate.

1               Claim 100 (original): A method in accordance with claim 88 in which said zinc is  
2       in the form of a member selected from the group consisting of zinc halide, zinc sulfate, zinc L-  
3       carnitiate, zinc L-carnitiate ascorbate and bis-ascorbate, zinc taurate, zinc taurine ascorbate and  
4       bis-ascorbate, zinc L-arginate, zinc L-arginine ascorbate and bis-ascorbate, zinc L-carnitiate, zinc  
5       L-carnitine ascorbate and bis-ascorbate, zinc phosphate, zinc acetate, zinc ascorbate, and zinc  
6       bis-ascorbate.

1               Claim 101 (original): A method in accordance with claim 88 in which said  
2       vanadium is in the form of a member selected from the group consisting of vanadate,  
3       peroxovanadate, vanadyl sulfate salts, and bis(maltolato)oxovanadium(IV).

1               Claims 102-103 (canceled)

1               Claim 104 (original): A method in accordance with claim 88 in which said  
2       chromium is in the form of a member selected from the group consisting of chromium  
3       dinicotinate, and chromium tripicolinate.